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SEP 1 0 2003

I. 510(k) Safety and Effectiveness Summary

A. *Contact Information*

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
610 Palomar Avenue
Sunnyvale, CA 94085

B. *Device Name*

Micrus Microcatheter
Device: Catheter, Intravascular, Diagnostic
Regulation Number: 870.1200
Product Code: DQO
Device Class: 2

C. *Predicate Device(s)*

Number	Description	Clearance Date
K960806	Tracker Excel 14 Microcatheter	05/02/96

D. *Device Description*

The Micrus Microcatheter consists of 4 major components:

- A flexible shaft with a lubricious liner extruded from Teflon. The liner is reinforced with a metal wire made from stainless steel. The outer shaft jacket is made from Pebax,
- An atraumatic distal flexible tip containing two radiopaque marker bands. The marker bands are useful in tracking catheter tip position and during placement of detachable embolic coils.
- A standard luer hub insert, which is molded onto the flexible shaft.
- A hydrophilic coating, which covers the distal 100 centimeters of the Microcatheter.

E. *Intended Use*

The Micrus Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature.

F. *Intended Use Predicate Device (per products' Instructions for Use)*

"The Target Therapeutics' Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature."

G. 510(k) Summary of Safety and Efficacy

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Corporation, it is concluded that the Micrus Microcatheter is substantially equivalent to the Boston Scientific/Target Therapeutics Microcatheter in safety and effectiveness.

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
June 27, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Micrus Corporation
c/o Mr. Morten Christensen
Underwriters Laboratories, Inc.
Office Coordinator
1655 Scott Boulevard
Santa Clara, CA 95050-4169

Re: K032624
Micrus Microcatheter
Regulation Number: 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: August 25, 2003
Received: August 26, 2003

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Device Name:

Micrus Microcatheter

510(k) Number (if known):

Indications for Use:

The Micrus MicroCatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: X
~~(Per 21 CFR 801.109)~~

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032624